THE CLAIMS

What is claimed is:

1. A propellant free buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a polar solvent in an amount between 30 and 99 percent by weight of the total composition.

2. The composition of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

3. The composition of claim 2, wherein the polar solvent is present in an amount between 37 and 98 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

4. The composition of claim 3, wherein the polar solvent is present in an amount between 60 and 97 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

5. The composition of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration.

6. The composition of claim 1, wherein the polar solvent comprises polyethylene glycol.

7. The composition of claim 1, wherein the polar solvent comprises ethanol.

8. The composition of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. A method of administering ondansetron or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 1.

10. The method of claim 9, wherein the amount of the spray is predetermined.

11. A buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount of between 0.1 and 25 percent by weight of the total composition;

a polar solvent in an amount between 10 and 97 percent by weight of the total composition; and

a propellant in an amount between 2 and 10 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

12. The composition of claim 11, further comprising a taste mask and/or flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

13. The composition of claim 12, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the taste mask and/or flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

14. The composition of claim 13, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and taste mask and/or flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

15. The composition of claim 11, wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration.

16. The composition of claim 15, wherein the polar solvent comprises polyethylene glycol.

17. The composition of claim 15, wherein the polar solvent comprises ethanol.

18. The composition of claim 12, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

19. The composition of claim 11, wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

20. A method of administering ondansetron or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 11.

21. The method of claim 20, wherein the amount of the spray is predetermined.

22. A propellant free buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and

a non-polar solvent in an amount between 30 and 99 percent by weight of the total composition.

23. The composition of claim 22, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

24. The composition of claim 23, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

25. The composition of claim 22, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

26. The composition of claim 25, wherein the solvent is a triglyceride.

27. A method of administering ondansetron or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 22.

28. The method of claim 27, wherein the amount of the spray is predetermined.

29. A buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount between 0.05 and 50 percent by weight of the total composition; and

a non-polar solvent in an amount between 19 and 85 percent by weight of the total composition; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or brancehed configuration.

30. The composition of claim 29, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

31. The composition of claim 30, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

32. A buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount between 0.01 and 40 percent by weight of the total composition;

a non-polar solvent in an amount between 25 and 89 percent by weight of the total composition;

a propellant in an amount between 10 and 70 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or brancehed configuration; and

a taste mask and/or flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

33. The composition of claim 32, wherein the propellant is present in an amount between 20 and 70 percent by weight of the total composition, the non-polar solvent is present in an amount between 25 and 75 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount from between 0.25 and 35 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 2 and 7.5 percent by weight of the total composition.

34. The composition of claim 29, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

35. The composition of claim 34, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

36. The composition of claim 29, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

37. The composition of claim 36, wherein the solvent is a triglyceride.

38. A method of administering ondansetron or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 29.

39. The method of claim 38, wherein the amount of the spray is predetermined.

40. A buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount between 0.2 and 10 percent by weight of the total composition; and

a polar solvent comprising propylene glycol and ethanol in an amount between 50 and 99 percent by weight of the total composition.

41. A propellant free buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1.

42. The composition of claim 40, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

43. The composition of claim 42, wherein the polar solvent is present in an amount between 37 and 98 percent by weight of the total composition, the ondansetron or a

pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

44. The composition of claim 43, wherein the polar solvent is present in an amount between 60 and 97 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

45. The composition of claim 41, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

46. The composition of claim 42, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

47. A method of administering ondansetron or a pharmaceutically acceptabl;e salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 41.

48. The method of claim 47, wherein the amount of the spray is predetermined.

49. A buccal spray composition for transmucosal administration of ondansetron or a pharmaceutically acceptable salt thereof comprising:

ondansetron or a pharmaceutically acceptable salt thereof in an amount between 0.05 and 50 percent by weight of the total composition;

a mixture of a polar solvent and a non-polar solvent in an amount between 10 and 97 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

50. The composition of claim 49, further comprising a taste mask and/or flavoring agent is present in an amount between 0.01 and 10 percent by weight of the total composition.

51. The composition of claim 50, wherein the propellant is present in an amount between 10 and 70 percent by weight of the total composition, the solvent is present in an amount between 20 and 97 percent by weight of the total composition, the ondansetron or a pharmaceutically acceptable salt thereof is present in an amount from between 0.1 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

52. The composition of claim 49, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

53. The composition of claim 52, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

54. The composition of claim 49, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

55. A method of administering ondansetron or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 49.

56. The method of claim 55, wherein the amount of the spray is predetermined.

57. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

58. The method of claim 57, wherein the emesis is caused by chemotherapy or radiation.

59. The method of claim 58, further comprising administering to the patient a corticosteroid.

60. The method of claim 58, further comprising administering to the patient dexamethasone.

61. The method of claim 58, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

62. The method of claim 61, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

63. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1 before the anesthesia is administered.

64. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

65. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 11.

66. The method of claim 65, wherein the emesis is caused by chemotherapy or radiation.

67. The method of claim 66, further comprising administering to the patient a corticosteroid.

68. The method of claim 66, further comprising administering to the patient dexamethasone.

69. The method of claim 66, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

70. The method of claim 69, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

71. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 11 before the anesthesia is administered.

72. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 11.

73. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 22.

74. The method of claim 73, wherein the emesis is caused by chemotherapy or radiation.

75. The method of claim 74, further comprising administering to the patient a corticosteroid.

76. The method of claim 74, further comprising administering to the patient dexamethasone.

77. The method of claim 74, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

78. The method of claim 77, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

79. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 22 before the anesthesia is administered.

80. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 22.

81. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 29.

82. The method of claim 81, wherein the emesis is caused by chemotherapy or radiation.

83. The method of claim 82, further comprising administering to the patient a corticosteroid.

84. The method of claim 82, further comprising administering to the patient dexamethasone.

85. The method of claim 82, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

86. The method of claim 85, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

87. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 29 before the anesthesia is administered.

88. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 29.

89. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 41.

90. The method of claim 89, wherein the emesis is caused by chemotherapy or radiation.

91. The method of claim 90, further comprising administering to the patient a corticosteroid.

92. The method of claim 90, further comprising administering to the patient a dexamethasone.

93. The method of claim 90, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

94. The method of claim 93, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

95. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 41 before the anesthesia is administered.

96. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 41.

97. A method of treating emesis in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 49.

98. The method of claim 97, wherein the emesis is caused by chemotherapy or radiation.

99. The method of claim 98, further comprising administering to the patient a corticosteroid.

100. The method of claim 98, further comprising administering to the patient dexamethasone.

101. The method of claim 98, wherein the oral mucosa of the patient is sprayed between about 5 minutes and 2 hours before chemotherapy or radiation therapy begins.

102. The method of claim 101, further comprising spraying the oral mucosa of the patient between about 1 hour and 6 hours after chemotherapy or radiation therapy ends.

103. A method of administering anesthesia to a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 49 before the anesthesia is administered.

104. A method of treating anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 49.